

QAQA

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT EM-ARC-02-10

OF THE

NATIONAL SPENT NUCLEAR FUEL PROGRAM

AT

IDAHO FALLS, IDAHO

SEPTEMBER 23 - 26, 2002

Prepared by: _____ Date: _____
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Approved by: _____ Date: _____
R. Dennis Brown
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of the Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance (OQA) audit EM-ARC-02-10, the audit team determined that with the exception of the six identified conditions adverse to quality, the National Spent Nuclear Fuel Program (NSNFP) is satisfactorily implementing the examined portions of the NSNFP Quality Assurance (QA) Program. The NSNFP QA Program was found to be compliant with the DOE/RW-0333P, Revision 12, *Quality Assurance Requirements and Description* (QARD) except for two conditions adverse to quality, which related to the NSNFP QA program not implementing QARD requirements.

The applicable QARD sections reviewed by the audit team were determined to be effectively implemented with the exception of elements 1.0, 7.0, and Supplement V. Section 1.0, "Organization," was determined to be unsatisfactory pending the resolution of NSNFP Corrective Action Report (CAR) 02-NSNF-AU-001-CAR-002, which pertains to the independence of the QA organizations from cost and schedule. Section 7.0, "Control of Purchased Items and Services," was determined to be unsatisfactory due to the Idaho National Engineering and Environmental Laboratory (INEEL) Spent Nuclear Fuel (SNF) Program being "conditionally qualified" without having a mechanism in the NSNFP to allow for such conditions. In addition, NSNFP CAR 02-NSNF-AU-001-CAR-001 documents a programmatic breakdown of this element and remains open. Supplement V was determined unsatisfactory based on a lack of procedure controls for electronic management of data activities being performed.

The six conditions adverse to quality resulted in the issuance of four Deficiency Reports (DR) and two Quality Observations in areas of implementing procedures, supplier qualification, control of electronic management of data, root cause analysis, and document review and revision.

The audit team evaluated the effectiveness of the corrective actions for three previously DRs issued as a result of last year's audit, EM-ARC-01-13. The audit team determined the corrective actions to be effective for these DRs, which have been closed.

The audit team identified noteworthy practices in the areas of training documentation and cross-checking, management tools used for deficiency tracking, records retrieval, and development/integration of the new implementing procedures.

2.0 SCOPE

The audit team conducted a compliance-based audit of the NSNFP in Idaho Falls, Idaho. The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed the adequacy and effectiveness of implementation of the NSNFP QA Program and applicable portions of the OCRWM QARD.

The audit team reviewed the status of three closed deficiency documents, issued as a result of the previous OQA audit, to determine the effectiveness of completed corrective actions by NSNFP.

In accordance with the approved audit plan, the following QA Program Sections were evaluated:

QARD Program Sections

1.0	Organization
2.0	QA Program
3.0	Design Control
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
11.0	Test Control
16.0	Corrective Action
17.0	QA Records
18.0	Audits
Supplement I	Software
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data

3.0 AUDIT TEAM

John R. Doyle, Navarro Quality Services (NQS)/Audit Team Leader
Patrick V. Auer, NQS/Auditor
Samuel E. Archuleta, NQS/Auditor
Christian M. Palay, NQS/Auditor

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at NSNFP offices on Monday, September 23, 2002. Daily debriefings were held to apprise NSNFP management and staff of the progress of the audit and any identified conditions adverse to quality. A post-audit meeting was conducted at NSNFP offices on Thursday, September 26, 2002. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, with the exception of those areas where conditions adverse to quality were identified, the NSNFP is satisfactorily and effectively implementing the examined portions of the QA Program and applicable implementing procedures. The results for each QARD Section evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Audit Activities

Attachment 2, "Summary Table of Audit Results," provide results for each QA Program Section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.3 Summary of Conditions Adverse to Quality

The audit identified conditions adverse to quality, which resulted in the issuance of four DRs, and two Quality Observations.

Synopses of the documented conditions adverse to quality are detailed below. The DRs have been transmitted to NSNFP under separate letter.

5.3.1 Deficiency Reports

EM(O)-03-D-004

Although NSNFP is conducting modeling activities, applicable NSNFP procedures, i.e., Program Support Organization (PSO) 3.03, Revision 1, "Engineering Analysis," and PSO 19-01, Revision 1, "Engineering Documentation," do not contain methodology for control and validation of models per QARD Section 3.0 (Design Control), and Supplement III (Scientific Investigation). In addition, Program Management Procedure (PMP) 6.01, Revision 6, "Review and Approval of NSNFP Internal Documents" omitted the QARD Section 2.0 (Quality Assurance Program) requirement that individuals other than the preparer perform document reviews.

EM(O)-03-D-005

PMP 7.01, Revision 0, "Quality Program Acceptance for DOE SNF Sites," requires that acceptance of a DOE SNF site QA Program be based on satisfactory resolution of inconsistencies identified via desk top reviews, surveillances or audits. Contrary to the above, memorandum (NSNFP QA Manager to Director INTEC Programs Division) dated 9/5/02, conditionally qualifies the INEEL SNF Program. Said memorandum identifies approximately 15 conditions adverse to quality and provides interim guidance for corrective measures. There is no provision in the NSNFP QA Program for conditional qualification.

EM(O)-03-D-006

QARD, Supplement V, "Control of Electronic Management of Data," requires that controls and processes be in place for the management of data that exists or are used in electronic format. The Goth_SNF Software Program is utilized for NSNFP quality-affecting activities and electronic files are routinely transferred from workstations to personnel computers and vice-versa. NSNFP does not have any implementing documents in

place to satisfy the QARD requirements identified in Supplement V for the control of the electronic management of data.

EM(O)-03-D-007

Procedure Quality Assurance Staff (QAS) 16.02, Revision 6, “Corrective Action,” requires that a root cause analysis be performed and submitted with the response to identified significant conditions adverse to quality. Contrary to these QAS requirements, no root cause was performed and, as a result, the root cause analysis documentation was not submitted with the response to CAR 02-NSNF-AU-001-CAR-001.

5.3.2 Quality Observations

The Quality Observation is used, based on the auditor’s discretion, to document a minor condition adverse to quality requiring only remedial action that has no residual impact and can reasonably be expected to be completed within 30 days.

EM(O)-03-O-005

Quality Observation, EM(O)-03-O-005, identifies that a required reviewer was not identified as a mandatory reviewer for the review of DOE/SNF/QAPP-001, Revision 1, “National Spent Nuclear Program Quality Assurance Program Plan” as per the requirements of PMP 6.01.

EM(O)-03-O-006

Change bars required by PMP 2.07, Revision 0, “Preparing the NSNFP Quality Assurance Program Plan and QARD Requirements Matrix,” were omitted from DOE/SNF/QAPP-001, Revision 1.

5.3.3 Follow-up of Previously Issued Deficiency Documents

EM-00-D-143. This condition adverse to quality identified the lack of performance-based audits conducted by the NSNFP in support of OCRWM-related work.

EM-00-D-144. This DR identified that Fiscal Year 2001 Quarterly NSNFP Assessment Schedules did not identify surveillances with unique numbers nor were the surveillances tracked through closure prior to being removed from the assessment schedule.

EM-00-D-145. This DR documented that corrective actions to internally generated deficiency documents were not being completed and closed in a timely manner.

6.0 LIST OF ATTACHMENTS

Attachment 1, "Personnel Contacted During the Audit"
Attachment 2, "Summary Table of Audit Results"

**ATTACHMENT 1
PERSONNEL CONTACTED DURING THE AUDIT**

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Arenaz, M. R.	DOE-ID/NSNFP/Manager	X	X	X
Armour, D. A.	NSNFP/QAS Manager	X	X	X
Blyth, R. L.	DOE-ID/NSNFP/QA Program Manager	X	X	X
Carlsen, Brett	NSNFP/Advisory Engineer		X	
Dahl, C. A.	NSNFP/Advisory Engineer		X	
Battan, Robert	NSNFP/Repository Analysis Project Engineer		X	
Davis, R. D.	DOE-ID QA Team Leader	X	X	X
Gladsen, Scott	NSNFP /Technical Lead			X
Hill, Thomas	NSNFP/Technical Lead	X	X	X
Loo, H. H.	NSNFP/Technical Lead		X	
MacKay, N. S.	NSNFP/PSO Quality Engineer	X	X	X
Morgan, Thomas	NSNFP/QA Specialist	X		
Morton, Keith	NSNFP/Transportation and Packaging Project Engineer		X	
McManamon, W. L.	NSNFP/Document Control/Records Management Coordinator		X	
Shelton-Davis, Colleen	NSNFP/ Materials and Technology, Project Engineer		X	
Passey, Tana	NSNFP/Training Coordinator	X	X	X
Wheatly, P. D.	NSNFP/ Project Manager	X	X	X

Legend: NSNFP National Spent Nuclear Fuel Program
 DOE-ID U.S Department of Energy-Idaho
 QAS Quality Assurance Staff

ATTACHMENT 2

SUMMARY TABLE OF AUDIT RESULTS

QA Program Sections	Implementing Documents	Details (✓) List	Deficiency Reports	QOs	Recommendations	Program Adequacy	Procedure Compliance	Overall
1	PMP 1.01, Rev. 2	Page 1	N	N	N	UNSAT	N/A	* UNSAT
	PMP 1.02, Rev. 0	Pages 1-5	N	N	N	SAT	SAT	
	PMP 1.03, Rev 0	Pages 6 -7	N	N	N	SAT	SAT	
2	PMP 2.01, Rev. 3	Page 8	N	N	N	SAT	SAT	SAT
	PMP 2.04, Rev 5	Pages 9-11	N	N	N	SAT	SAT	
	PMP 2.05 Rev. 4	Page 12-15	N	N	N	SAT	SAT	
	PMP 2.07 Rev. 0	Pages 16-18	N	EM(O)-03-O-006	N	SAT	SAT	
	PMP 2.08, Rev. 0	Pages 19-20	N	N	N	SAT	SAT	
	PMP 2.09, Rev. 0	Page 21	N	N	N	SAT	SAT	
3	PSO 3.01, Rev. 2	Pages 22-25	N	N	N	SAT	SAT	SAT
	PSO 3.03, Rev. 0	Page 25	EM(O)-03-D-004	N	N	SAT	SAT	
	PSO 3.04, Rev. 0	Page 25	EM(O)-03-D-004	N	N	SAT	SAT	
4	PSO 4.01, Rev. 3	Pages 26-28	N	N	N	SAT	SAT	SAT
	PSO 4.02, Rev. 0	Pages 29-30	N	N	N	SAT	SAT	
5	PMP 5.01, Rev. 4	Pages 31-33	N	N	N	SAT	SAT	SAT
	PMP 5.05, Rev. 0	Pages 34-35	N	N	N	SAT	SAT	
6	PMP 6.01, Rev. 6	Pages 36-37	EM(O)-03-D-004	EM(O)-03-O-005	N	SAT	SAT	SAT
	PMP 6.03, Rev. 0	Pages 38-40	N	N	N	SAT	SAT	
	PMP 6.04, Rev. 0	Pages 41-42	N	N	N	SAT	SAT	

QA Program Sections	Implementing Documents	Details (✓) List	Deficiency Reports	QOs	Recommendations	Program Adequacy	Procedure Compliance	Overall
7	PMP 7.01, Rev. 0	Pages 43-44	EM(O)-03-D-005	N	N	UNSAT	UNSAT	UNSAT
	PMP 7.02, Rev. 0	Pages 45-48	N	N	N	SAT	SAT	
	PMP 7.03, Rev. 0	Pages 49-50	N	N	N	SAT	SAT	
11	PSO 11.01, Rev. 1	Pages 51-53	N	N	N	SAT	SAT	SAT
16	QAS 16.02, Rev. 6	Pages 54-55	EM(O)-03-D-007	N	N	SAT	SAT	SAT
	QAS 16.03, Rev. 2	Pages 56-57	N	N	N	SAT	SAT	
	QAS 16.04, Rev. 2	Page 58	N	N	N	SAT	SAT	
17	PMP 17.01, Rev.4	Pages 59-61	N	N	N	SAT	SAT	SAT
	PMP 17.03, Rev. 0	Pages 62-64	N	N	N	SAT	SAT	
18	QAS 18.01, Rev. 4	Pages 65-67	N	N	N	SAT	SAT	SAT
	QAS 18.02, Rev. 6	Pages 68-72	N	N	N	SAT	SAT	
	QAS 18.03, Rev. 5	Pages 73-75	N	N	N	SAT	SAT	
	QAS 18.04, Rev. 4	Pages 76-77	N	N	N	SAT	SAT	
SI	PSO 19.01, Rev. 2	Pages 78-85	EM(O)-03-D-004	N	N	SAT	SAT	SAT
SIII	Scientific Investigation	Pages 86-91	N	N	N	SAT	N/I	SAT
SV	Control of the Electronic Management of Data	Pages 92-94	EM(O)-03-D-006	N	N	UNSAT	UNSAT	UNSAT
TOTAL		94	4	2	0			

** Refer to 1.0 Executive Summary, page 2, second paragraph*

Legend: N None SAT Satisfies Criteria
 N/A Not Applicable UNSAT Does not satisfy Criteria
 N/I Not Implemented

